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Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

By Nina L. McNeill

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PATENT

Docket No.: 018158-018610US

Customer No. 20350

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Lawrence W. Stark et al.

Application No.: 10/006,992

Filed: December 6, 2001

For: DIRECT WAVEFRONT-BASED  
CORNEAL ABLATION TREATMENT  
PROGRAM

Technology Center: 3700

Confirmation No.: 1090

Examiner: David M. Shay

Art Unit: 3739

**APPEAL BRIEF**

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal received by the U.S. Patent and Trademark Office on November 21, 2005, this Brief is submitted in appeal of the final Office Action mailed August 24, 2005, and also addresses the Advisory Action mailed December 23, 2005.

**I. REAL PARTY IN INTEREST**

VISX Incorporated, the assignee of record.

**II. RELATED APPEALS AND INTERFERENCES**

None

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**III. STATUS OF CLAIMS**

Claims 1-17 and 21-35 are canceled. Claims 18-20 and 36-42 are pending, and stand rejected. Claims 18-20 and 36-42 are appealed. All pending claims are presented in **Appendix A.**

**IV. STATUS OF AMENDMENTS**

Subsequent to the final rejection of August 24, 2005, an Amendment After Final was filed on November 21, 2005. This Amendment After Final was acted upon by the Examiner, but was denied entry as noted in the Advisory Action mailed December 23, 2005.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

The claimed subject matter involved in this appeal is directed to a method of determining an accuracy of a gradient array in an optical tissue measurement. The method of presently pending claim 18, which is the sole independent claim, includes transmitting an image through the optical tissue, determining local gradients of the array across the optical tissue from the transmitted image, integrating along a closed integration path across a portion of the array, and determining the accuracy of the gradient array based on the integration. These elements are discussed in the application at, for example, page 9, line 15 to page 13, line 4, and in Figures 3 to 5.

**VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. Whether claims 18-20 and 36-42 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 6,563,105 to Seibel et al. [“Seibel”] in combination with U.S. Patent No. 6,280,435 to Odrich et al. [“Odrich”] and U.S. Patent No. 6,486,943 to Burns et al. [“Burns”].

**VII. ARGUMENT**

**Rejection under 35 U.S.C. §103 over Seibel in combination with Odrich and Burns**  
**Claims 18-20 and 36-42**

The only grounds of rejection apply to a group of claims (18-20 and 36-42), and the claims are argued as a group.

**1. The Examiner's rationale**

The Examiner's position is stated in the Office Action of March 29, 2005, and elaborated in the Final Office Action of August 24, 2005 and the Advisory Action of December 23, 2005. In particular, the Examiner alleges that presently pending independent claim 18 is unpatentable because:

"It would have been obvious to employ the refractometer of Burns in the method of Odrich et al and to produce the contour data by the close integration path of Seibel et al, since Odrich et al discusses no method to produce the contour data required for the method, thus producing a method such as claimed." (See page 2 of the March 29, 2005 Office Action, and page 3 of the August 24, 2005 Final Office Action).

**2. Applicable Law**

The law regarding obviousness is discussed in certain decisions (copies enclosed) and also in MPEP §§ 2142, 2143, and 2112 as set forth below.

**a. Application of Royka (490 F.2d 981, 180 USPQ 580)**

This case recites the rule that a *prima facie* case of obviousness must show that the cited references, when combined, teach or suggest all of the claimed elements. At issue was whether any of the cited references disclosed use of a xerographic toner, which was recited in the claims. The court found none of the references described xerographic technology, and therefore the obviousness rejection was improper.

**b. In re Vaeck (947 F.2d 488, 20 U.S.P.Q. 2d 1438)**

This case reiterates that a *prima facie* case of obviousness requires that the cited references must provide a teaching or suggestion to make the claimed combination. At issue was whether the art worker would have been motivated to combine *Bacillus* DNA, which was discussed in one reference, with

Cyanobacteria DNA, which was discussed in another reference. The court ruled that the cited references provided no motivation to make the proposed combination, and therefore the *prima facie* obviousness was improper.

**c. Mehl/Biophile International Corp. v. Milgraum (192 F.3d 1362, 52 U.S.P.Q. 2d 1303)**

This case reinforces the principle that inherency requires the alleged feature to naturally flow from the cited reference. At issue was whether a claimed laser treatment element was inherently described in either (a) a manual for tattoo removal or (b) a journal article describing guinea pig epilation. The court ruled that the claim element of aligning a laser light applicator over a hair follicle opening was not inherently disclosed in the tattoo removal manual, because a tattoo location may or may not contain a hair follicle. On the other hand, the court found that the claim element was inherently disclosed in the guinea pig article, because laser treatment of a guinea pig necessarily involves alignment of a laser over a hair follicle, due to the prevalence of hair follicles on the treated area.

**d. In re Dembiczak (175 F.3d 994, 50 U.S.P.Q. 2d 1614)**

The rule regarding impermissible hindsight is further illustrated by this case. The issue was whether a patent claim for a trash bag decorated to resemble a pumpkin was properly rejected on grounds of obviousness. The court found that a *prima facie* case of obviousness had not been established because the rejection was based on a reference-by-reference, limitation-by-limitation analysis. There was no teaching or suggestion to combine children's art references with conventional trash or lawn bag references.

**e. MPEP § 2143 Requirements of a *Prima Facie* Case of Obviousness**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure."

f. **MPEP § 2112 (IV) Inherency**

This section of the MPEP provides the following guidance regarding inherency: The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.

[ . . . ] To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. [ . . . ] In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

g. **MPEP § 2142 Legal Concept of *Prima Facie* Obviousness**

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon

applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

### 3. Analysis

The foregoing court decisions and MPEP provisions clearly establish that the cited references, when combined, must expressly or implicitly teach all the claim limitations, and that there must be some motivation to combine the references that is not based on hindsight.

#### a. Claim Elements Not Taught by References

Presently pending independent claim 18 is drawn to a method for determining an accuracy of a gradient array in an optical tissue. The method includes the steps of *i*) transmitting an image through the optical tissue, *ii*) determining local gradients of the array from the transmitted image, *iii*) integrating along a closed integration path across a portion of the array, and *iv*) determining the accuracy of the gradient array based on the integration.

Advantageously, as noted in the specification at page 12, line 27 to page 14, line 21, by performing an integration it is possible to detect and identify inaccuracies in the gradient array. Relatedly, as noted in the specification at, for example, page 14, lines 11-15, embodiments of the present invention provide for the capability of detecting bad Hartmann-Shack data along a path by an integration technique.

#### 1). U.S. Patent No. 6,563,105 to Seibel et al.

In general, Seibel describes ultrathin fiber optic endoscopy, wherein an object is illuminated with a fiber, and data associated with reflected light is integrated to provide surface information. More specifically, Seibel reports image acquisition devices that can selectively illuminate a target by vibrating an optical fiber. [Seibel, Fig. 1; col. 1, lines 17-23; col. 4, lines 14-25] Seibel's devices seek to characterize the target surface based on signals reflected from the target surface and detected near the vibrating fiber. [*Id.*] Seibel describes integration of orientation values derived from those reflected signal along arbitrary curves or closed paths, but

acknowledges that the noisy signals received by that system may require that, in practice, the use of optimization techniques or the like may have to be employed in order to recover smooth surfaces. [*Id.* at col. 17, lines 31-36]

Seibel does not teach i) transmitting an image through optical tissue, ii) determining local gradients from an image that has been transmitted through optical tissues, iii) integration across a gradient field based on image transmitted through tissues, nor iv) determining an accuracy of any gradient array based on an integration. As far as Appellants understand the applicability of this reference, it is cited for the proposition that integration along a closed path is known. Appellants note, however, that the Seibel reference integrates only imaging data reflected from a surface to attempt to recover surface depth information, and that such a disclosure appears largely (if not completely) irrelevant to the presently claimed invention.

In an apparent inherency argument (see August 24, 2005 Office Action at page 2, lines 9-11; and December 23, 2005 Advisory Action at page 2, lines 3-4), the Examiner seems to allege that determining the accuracy of the gradient array is a necessary consequence of Seibel's integration. Applicants disagree, and note that the record is devoid of any established support whatsoever for any assertion that Siebel would inherently or implicitly make use of any one of the method steps recited by claim 18. To satisfy the requirements regarding inherency as discussed in *Mehl/Biophile* and MPEP §2112 (IV), the Examiner would have to establish that the accuracy determination must flow as a natural consequence from the technological constraints of Seibel. Applicants submit that Seibel sustains no such finding. In fact, contrary to the Examiner's inherency argument, it is entirely possible to perform an integration without determining the accuracy of the array. The optimization actually suggested by Siebel can proceed without any asserted need for such an array accuracy determination.

As a reference directed to surface depth data, Seibel is reminiscent of U.S. Patent No. 6,011,625 to Glass, which was cited in a previous Office Action dated March 10, 2004 and subsequently withdrawn as a reference. Glass similarly discusses an integration approach for characterizing surface information (e.g. terrain heights). Applicants submit that Seibel's surface characterization is no more relevant to the presently claimed invention than was Glass's surface characterization, and that the rejections relying on this reference should also be withdrawn.

**2) U.S. Patent No. 6,280,435 to Odrich et al.**

Odrich is cited for the proposition that spatially resolved refractometers can be used to map the surface contour of the cornea. However Odrich has not been shown to teach or disclose determining the accuracy of a gradient array based on any integration, much less the detailed method steps presently recited in claim 18.

**3) U.S. Patent No. 6,486,943 to Burns et al.**

Burns is cited for the proposition that spatially resolved refractometers that transmit images through the cornea are known. Yet Burns has again not been shown to teach or disclose determining the accuracy of a gradient array based on any integration, as presently claimed.

In sum, Seibel fails to teach or suggest the step of determining the accuracy of a gradient array based on the integration, and Odrich and Burns fail to remedy this deficiency. Thus, the combination of elements does not teach all of the presently claimed elements, and therefore cannot support a *prima facie* obviousness rejection, as set out in *Application of Royka* and MPEP §2143.

**b. Motivation to Combine References Not Established**

As noted above, the Examiner alleges that:

“It would have been obvious to employ the refractometer of Burns in the method of Odrich et al and to produce the contour data by the close integration path of Seibel et al, since Odrich et al discusses no method to produce the contour data required for the method, thus producing a method such as claimed.”

As Applicants understand the Examiner’s argument, the Examiner asserts that Odrich describes a surface refractometer for mapping corneal surface contours, but does not describe a method to produce the resulting contour data. The Examiner alleges the artisan would be motivated to use Seibel’s surface endoscopy integration method therefore to produce such surface contour data, but instead of using the Odrich corneal surface refractometer, the artisan would allegedly be motivated to use the subsurface refractometer of Burns.

The Examiner does not state, however, why the artisan would be motivated in the first place to use the subsurface refractometer of Burns instead of the surface refractometer of

Odrich. What is more, the Examiner does not explain why the artisan would be motivated to pick and choose different parts of the Burns reference, the Odrich reference, and the Seibel reference to provide an accuracy determination that is absent from all of these references. As an example of why the present rejections fail to set forth a reasonable basis for *prima facie* obviousness, Applicants understand the Examiner to assert that the artisan would allegedly be motivated to use the subsurface refractometer of Burns, but would disregard the various corresponding subsurface optical tissue analysis methods described by Burns (e.g. col. 9, line 37 to col. 16, line 6) and instead use the surface analysis methods described by Seibel. Yet the Examiner provides no explanation for the substitution, and absent a reasonable motivation for altering the actual disclosure of the references themselves or combining the references as discussed in *In re Vaeck* and MPEP §2143, the rejection must be withdrawn.

**c. Hindsight Reasoning is Impermissible**

As noted in MPEP §2142 and *In re Dembicza*k, it is improper to rely upon hindsight to support a finding of obviousness. It is respectfully submitted that the Examiner's proposed scheme of reasoning requires considerable mental gymnastics in selectively picking and choosing between elements of three separate references, and prodigious imagination in leaping gaps between the very different systems described in those references. Such a scheme is much easier to construct in hindsight with knowledge of the presently claimed invention than it would be prospectively. It is in precisely such circumstances that the requirement for evidence of particularized motivation is most acute as a safeguard against hindsight. However, the motivation relied on here is neither particularized to the presently claimed invention nor supported by an evidentiary source. In the absence of such a safeguard, the case of obviousness appears to be the result of the Examiner stitching together bits and pieces of the cited references using the Applicant's disclosure as a blueprint, and thus constitutes impermissible hindsight. The suggestion or motivation to combine references must not come from the Applicant.

As noted in MPEP 2143.03, if an independent claim is nonobvious, then the claims depending therefrom are nonobvious as well. Therefore, claims 19, 20, and 36-42 depend either

directly or indirectly, and therefore are allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite.

**4. Conclusion**

It has not been shown that the cited references when combined teach all the claim elements, nor has any motivation to combine the references been established that is not based on hindsight. Thus, the Examiner has not met the burden of establishing a *prima facie* case of obviousness. Reversal of this outstanding rejection is respectfully requested.

**VIII. CLAIMS APPENDIX**

A copy of the claims involved in the appeal is attached as Appendix A.

**IX. EVIDENCE APPENDICES**

Copies the decisions discussed above are attached as Appendices B-E.

**X. RELATED PROCEEDINGS APPENDIX**

Not Applicable.

Respectfully submitted,



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Attachments:

- Appendix A: Claims
- Appendix B: Application of Royka
- Appendix C: In re Vaeck
- Appendix D: Mehl/Biophile International Corp. v. Milgraum
- Appendix E: In re Dembiczak

**Appendix A: Pending claims**

1-17. (Canceled)

18. (Previously Presented) A method of determining an accuracy of a gradient array in an optical tissue measurement comprising:

transmitting an image through the optical tissue;

determining local gradients of the array across the optical tissue from the transmitted image;

integrating along a closed integration path across a portion of the array; and determining the accuracy of the gradient array based on the integration.

19. (Original) The method of claim 18, further comprising:

calculating a change in elevation along the closed integration path across the portion of the array.

20. (Original) The method of claim 18 wherein, the closed integration path comprises:

a common starting point, a common ending point, a first integration path connecting the common starting point to the common ending point, and a second integration path connecting the common starting point to the common ending point, the first and second integration paths being different.

21-35. (Canceled)

36. (Previously Presented) The method of claim 18, further comprising transmitting a source image from a light source posteriorly through the optical tissues and onto the retina to define the image, wherein the image is transmitted posteriorly through a central region of the cornea, the central region having a size which is significantly less than a pupil size

of the eye, and wherein the image is transmitted from the retina anteriorly through the optical tissues.

37. (Previously Presented) The method of claim 36, wherein the image is transmitted by the optical tissues as a plurality of beamlets, wherein each gradient corresponds to an associated portion of an optical surface such that each beamlet is transmitted through the optical tissue according to the corresponding gradient.

38. (Previously Presented) The method of claim 18 wherein the integration is performed so as to map an error-correcting change in optical tissues.

39. (Previously Presented) The method of claim 38 wherein the mapping step comprises deriving a proposed change in the optical tissue surface elevations so as to effect a desired change in optical properties of the eye, and further comprising modifying the optical tissue surface according to the proposed change by laser ablation.

40. (Previously Presented) The method of claim 18, wherein the closed integration path extends from a first center of a first portion of the optical surface to a second center of a second portion of the optical surface, from the second center to a third center of a third portion of the optical surface, and from the third center back to the first center, the first, second and third portions of the optical surface corresponding to the first, second and third gradients of the gradient array, respectively.

41. (Previously Presented) The method of claim 18, wherein the closed integration path extends from an initial location corresponding to a position between a first gradient array element and a second gradient array element, the path crossing a first portion of the optical surface corresponding to the second gradient array element, a second portion of the optical surface corresponding to a third gradient array element, and a third portion of the optical surface corresponding to a fourth gradient array element before returning back to the initial location.

42. (Previously Presented) The method of claim 18, wherein an elevation map is generated directly in the mapping step without deriving coefficients of a series expansion mathematically approximating the optical surface.

United States Court of Customs and Patent Appeals.  
 Application of Stephen F. ROYKA and Robert G. Martin.  
**Patent Appeal No. 9092.**

Feb. 7, 1974.

Appeal from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of patent application, Serial No. 648,701, for a 'responsive answer system.' The Court of Customs and Patent Appeals, Rich, J., held that an answer sheet for use in self-instruction and testing, in which were printed in 'response areas' meaningful information in permanent printing and confusing information in printing which could be removed, as by an erasure, both being legible so that a student, seeing a choice of answers to a question, was required to make a selection, the correctness of the selection being shown by the information which was then removed by the erasure, was not anticipated by prior patents and was therefore patentable.

Reversed.

West Headnotes

**Patents** **66(1.20)**

**291k66(1.20) Most Cited Cases**

"Responsive answer system," answer sheet for use in self-instruction and testing, in which were printed in "response areas" meaningful information in permanent printing and confusing information in printing which could be removed, as by erasure, both being legible so that student, seeing a choice of answers to question, was required to make selection, correctness of selection being shown by information which was then removed by erasure, was not anticipated by prior patents and was therefore patentable. 35 U.S.C.A. §§ 102, 103.

**Patents** **328(2)**

**291k328(2) Most Cited Cases**

3,055,117, 3,364,857. Cited.

**Patents** **328(1)**

**291k328(1) Most Cited Cases**

356,695. Cited.

\***981** Michael H. Shanahan, Rochester, N.Y., of record, for

appellant; Thomas M. Webster, Rochester, N.Y., Boris Haskell, Washington, D.C. (Paris, Haskell & Levine), Washington, D.C., of counsel.

Joseph F. Nakamura, Washington, D.C., for the Commissioner of Patents. Fred W. Sherling, Washington, D.C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE and MILLER, judges.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 28 and 30-36 of application serial No. 648,701, filed June 26, 1967, entitled 'Responsive Answer System.' We reverse.

The Invention

The appealed claims are directed to a device in the nature of an answer sheet for use in self-instruction and testing. The answer sheet may be associated with questions or separate therefrom. The essential features of the invention are that there are printed on the answer sheet in 'response areas' meaningful information in permanent printing and confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer. The following figures from the drawings are illustrative:

PERMANENT MEANINGFUL INFORMATION PLUS REMOVABLE CONFUSING INFORMATION	PERMANENT INFORMATION
--	-----------------------

A. TRUE

Y NO

E

S

A.

Y

E

S

WRONG

B. FALSE

N YES

O

RIGHT

B.

N

O

FIG. IA

FIG. IB

Fig. 1A shows two response areas to a given question before any removing action \*982 by the student has taken place and Fig. 1B shows the permanent information remaining in each after erasure of the removable information. Of course, if the student makes an initial choice of area A, showing up 'YES' or some other indication of a correct answer, he will not need to proceed further and erase the B area. In a modified form of the invention, a wrong selection, plus erasure, may expose, instead of or in addition to a statement that the answer is wrong, a number or other reference to further material which is to be studied.

A preferred method of printing the permanent meaningful information and the removable confusing information is by that type of xerography in which a fusible toner is used, the permanence of the printing depending on the extent to which the toner image is 'fixed' or fused by heat. By successive printings of the two kinds of information with fixing to different degrees, one image can be made permanent and the other made subject to easy removal, both images retaining such similarity of appearance that the user of the answer sheet cannot tell them apart.

Claim 28 is the principal claim, all others being dependent thereon, and reads as follows:

28. A device for selectively indicating information comprising

a support having response areas for presenting information for selection,

permanent printing indicative of meaningful information permanently fixed to said support within a response area, and

removable printing indicative of confusing information removably fixed to said support within a response area,

said meaningful and confusing information being substantially legible even when said permanent and removable printing are fixed over one another on said support,

said permanent and removable printing being substantially similar such that an observer cannot determine which information is permanent and which is removable

whereby the information within a response area is selected by attempting to remove the printing therein with the failure to remove printing identifying meaningful information.

Claims 30-36 add limitations which need not be considered except for noting that claims 33 and 34 alone specify the use of a xerographic toner, for which reason they were rejected on a different ground from the other claims.

#### The Rejection

The following references were relied on:

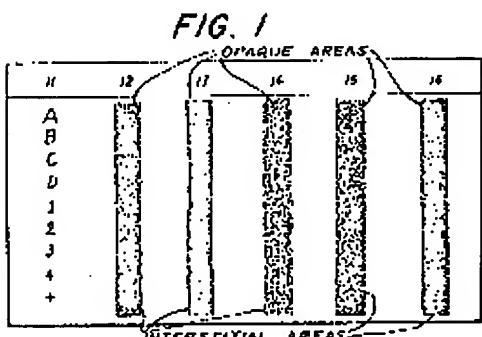
Reid et al. (Reid)	356,695	Jan. 25, 1887
Bernstein et al. (Bernstein)	3,055,117	Sep. 25, 1962
Lein et al. (Lein)	3,364,857	Jan. 23, 1968 (filed Feb. 2, 1966)

Claims 28, 30, 31, and 32 were rejected as anticipated under 35 U.S.C. § 102 by Bernstein; claims 28, 31, 32, 35, and 36 were rejected as anticipated under § 102 by Reid; and claims 33 and 34 were rejected under 35 U.S.C. § 103 for obviousness, on either Bernstein or Reid in view of Lein. These were the examiner's rejections and the board affirmed them, adhering to its decision on reconsideration.

Bernstein discloses an answer sheet in which printed information representing a response is 'temporarily concealed from the observer' and he discloses a number of different ways of effectively concealing the response. His specification states:

The objects of the invention are accomplished by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable and thus conceal the presence, absence, nature or position of the response from the participant. This may be effectuated by careful attention being paid to a number of factors including the design, \*983 color and position of the hiding or confusing media.

Fig. 1 of Bernstein's drawings, illustrates some of his concealing means:



following is the written description:

Referring now to the drawing, FIG. 1 illustrates some of the many optically confusing patterns which may be positioned between the printed structure to be concealed and the point of observation. Column 11 shows the information which is to be concealed. This information is repeated in columns 12 through 16 but in each case is concealed by a pattern in accordance with the present invention. Column 12 utilizes a pattern comprising an alphabetical maze in both line and half tone screen. Column 13 utilizes a pattern comprising an absorbing field having a plurality of irregular dot-like interstices. Column 14 utilizes a pattern comprising a maze of plus signs combined with dots. Columns 15 and 16 illustrate irregular and non-repetitious patterns.

Bernstein says that if at least 50% Of the response is

actually covered by the opaque portions of the confusion pattern, complete concealment is obtained. He also says that added means of concealment may be used, such as scoring and embossing and perforating the paper in order to scatter the light or let it shine through.

Reid is entitled 'Transformation Picture and Print.' The invention is said to be useful for advertisements, Christmas cards, birthday cards, valentines, and the like and as a source of amusement and instruction for children. It consists of a picture or print, part of which is permanently printed and part of which is removable from the paper on which it is printed. For the latter various soluble undercoatings or inks are described. If the picture is washed with a solvent, which may be water, the removable part disappears and the pictorial and/or typographic matter changes. The invention is illustrated by a typical nineteenth century temperance propaganda piece depicting the evils of drink. In the finished picture there are three scenes from left to right: Scene 1, the innocent child leads her father home from the pub; Scene 2, Father sits slumped in the kitchen chair with his bottle beside him, the family wash hanging above his head, this picture being entitled 'The Effects of Drink'; Scene 3, Mother stands in front of a sign reading 'Pawn Shop.' Across the bottom of the picture is a legend which says 'Wash the above and see what water will do.' Fig. II shows the result of washing with water: Scene 1, a handsome young man and his happy daughter stroll on the street; Scene 2, Father sits erect in a well-appointed room at a clothcovered table, apparently having a cup of tea, obviously a gentleman; Scene 3, Mother beams from the sideline and the Pawn Shop sign has vanished. Two new subscriptions appear and the words 'The' and 'Drink' have disappeared, the resultant being a new picture title reading 'The Beneficial Effects of Temperance.' 'The Beneficial' and 'Temperance' were covered by some soluble opaque in the original picture. No doubt the overall effect is instruction. Perhaps there was amusement in bringing about the transformation.

Lein relates to xerography and is relied on only for its disclosure of the removability of partially fused toner and the permanence of fully fused toner.

#### OPINION

As to the § 102 anticipation rejections, it will suffice to consider independent claim 28. If it is not fully met by Reid \*984 or Bernstein, neither are the more limited dependent claims. It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of legible meaningful and legible confusing information simultaneously, between which the user of the device may make a selection before he undertakes to remove any of the information from the response area selected by him. The element we find most clearly missing, contrary to the reasoning of the examiner and the board, is the legible confusing information. The Patent Office proposes to read this limitation on Bernstein's confusion patterns which are nothing but meaningless obscuring screens, conveying no information and providing the user with no basis for making a selection, as called for by claim 28. In appellants' device the legible confusing information-- i.e., the wrong answers-- are legible in the sense that they can be read as intelligible words, not merely a jumble of type serving to obscure the words of the wrong answers.

Appellants were fully aware of Bernstein and discussed its disclosures in their specification, distinguishing from this and other prior art, saying, in part:

The inventive concept hereof confuses not by physical blocking as taught by the prior art, but by compounding, associating (including disarranging) permanent information with confusing information, usually at least some of which is similar in character to the permanent information as to render it impossible to tell which is permanent and which is removable confusing information. In the invention, generally no attempt is made to designedly physically cover the permanent information, but to confuse it beyond interpretation by the presentation of extraneous removable, confusing information.

Claims are not to be read in a vacuum and while it is true they are to be given the broadest reasonable interpretation during prosecution, their terms still have to be given the meaning called for by the specification of which they form a part. We cannot read the terms 'legible' and 'information' on Bernstein's confusion patterns, as did the examiner and the

board. They are not 'legible,' as appellants use the term, and they convey no information.

As to anticipation by Reid, we find neither appellants' basic concept nor the substance of claim 28 to be disclosed. Apparently the solicitor could find little to support the rejection in Reid for all he says in his brief-- so far as claim 28 is concerned-- is:

Reid discloses a sheet which may be used for instruction and which may have a removable design partly covering a fixed design \* \* \*. Therefore, the disclosure of the reference encompasses the arrangement wherein a removable design covers a fixed design with both designs being substantially legible.

But claim 28 does not call for an arrangement wherein a removable design covers a fixed design. It calls for response areas, which Reid does not have, containing meaningful information in permanent printing together with removable printing conveying confusing information, both legible at the same time, between which a 'selection' can be made. The only choice offered to the user by Reid is to follow the instruction to wash the whole visible picture with water or other solvent, thus removing the overprinting, to discover what the permanent picture is. The Patent Office attempt to read claim 28 on this reference is a tour de force. We hold that Reid does not anticipate for failure to meet the limitations of claim 28 to 'response areas,' to the presentation of two categories of information (meaningful-permanent and removable-confusing) within such areas, and the possibility of selection. Anticipation requires a finding that the claimed invention be disclosed. It is not enough to say that appellants' invention and the reference are \*985 both usable for instruction and both consist of permanent and removable printings on paper, as did the solicitor.

The dependent claims rejected with claim 28, as anticipated under § 102, are not anticipated since claim 28 is not anticipated. Some of them merely add features which are disclosed by the references and some do not. Insofar as they do not, they further negative anticipation. The examiner recognized this fact as to claims 33 and 34, which are limited to xerography, and therefore did not reject them

under § 102. Similarly, he did not reject claim 30 on Reid or claims 35 and 36 on Bernstein. We find that claims 35 and 36 contain limitations which additionally distinguish from Reid. We have already noted that Reid had no 'response areas' as required by claim 28 and so Reid does not disclose the structure of claim 35 which additionally requires both the correct and incorrect answers to appear within the same response area.

As to claim 36, the examiner said it 'is merely a printed matter variation of the design of the reference,' Reid. This is not a valid reason for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated. We have commented on this matter In re Jones, 373 F.2d 1007, 54 CCPA 1218 (1967); and In re Miller, 418 F.2d 1392, 57 CCPA 809 (1969), and will not repeat ourselves. The limitations of claim 36 are not remotely suggested by Reid.

There remains the § 103 rejection of claims 33 and 34. Do they, taken together with all of the limitations of claim 28 from which they depend, define obvious subject matter? The difference between claim 28 and these two dependent claims is that they add the limitations to xerography. If Bernstein and Reid showed the claimed invention except for xerography, the addition of the Lein reference would make the subject matter of the claims obvious. But that is not the situation here. Adding the knowledge of xerographic technology to Bernstein or Reid still does not make the invention of claims 33 and 34 obvious for the same reasons we have given above in discussing anticipation. The essence of appellants' invention, as set forth in claim 28, is still missing notwithstanding the addition of the Lein reference and we see nothing in the combinations of references which would have made the invention obvious to one of ordinary skill in the art at the time it was made. We will, therefore, reverse this rejection.

The decision of the board is reversed.

Reversed.

490 F.2d 981, 180 U.S.P.Q. 580

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United States Court of Appeals,  
Federal Circuit.

In re Mark A. VAECK, Wipa Chungatupornchai and Lee  
McIntosh.  
No. 91-1120.

Oct. 21, 1991.

Inventor sought patent for claimed invention directed to use of genetic engineering techniques for production of insecticidal proteins. The United States Patent and Trademark Office Board of Patent Appeals and Interferences affirmed an examiner's rejection of certain claims, and appeal was taken. The Court of Appeals, Rich, Circuit Judge, held that: (1) patent application was improperly rejected on ground of prima facie obviousness, and (2) patent application was properly rejected to extent that claims were too general to enable person skilled in art to make and use claimed invention without undue experimentation.

Affirmed in part, reversed in part.

Mayer, Circuit Judge, dissented and filed opinion.

West Headnotes

[1] Patents 314(5)

291k314(5) Most Cited Cases

Obviousness of invention for which patent is sought is legal question which court independently reviews, though based upon Patent and Trademark Office's underlying factual findings, which court reviews under clearly erroneous standard. 35 U.S.C.A. § 103.

[2] Patents 16(2)

291k16(2) Most Cited Cases

In reviewing rejection of invention for patent as obvious in view of combination of prior art references, court considers whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that in so making or carrying out, those of ordinary skill would have reasonable expectation of success; both suggestion and reasonable expectation of success must be found in prior art, not in applicant's

disclosure. 35 U.S.C.A. § 103.

[3] Patents 16.25

291k16.25 Most Cited Cases

Patent application for genetic engineering techniques for production of insecticidal proteins was improperly rejected on ground of prima facie obviousness; prior art did not disclose or suggest expression in cyanobacteria of chimeric gene encoding insecticidally active protein, or convey to those of ordinary skill reasonable expectation of success in doing so. 35 U.S.C.A. § 103.

[4] Patents 99

291k99 Most Cited Cases

To be patentable, specification of patent must enable any person skilled in art to which it pertains to make and use claimed invention without undue experimentation. 35 U.S.C.A. § 112.

[5] Patents 99

291k99 Most Cited Cases

Patent application for using genetic engineering techniques to produce insecticidal proteins was properly rejected to extent that claims were too general to enable person skilled in art to make and use claimed invention without undue experimentation; claim referred to use of cyanobacteria in general as host organism, despite fact that cyanobacteria were diverse and relatively poorly studied group of organisms, comprising some 150 different genera, with successful use of any one type in manner called for in invention being unpredictable. 35 U.S.C.A. § 112.

[6] Patents 99

291k99 Most Cited Cases

Although patent applicants are not required to disclose every species encompassed by their claims, even in unpredictable art, in order to satisfy enablement requirement for patentability, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use invention as broadly as it is claimed. 35 U.S.C.A. § 112.

Patents 328(2)

291k328(2) Most Cited Cases

4,695,455. Cited.

\*489 Ian C. McLeod, Ian C. McLeod, P.C., Okemos, Mich., argued for appellant.

Teddy S. Gron, Associate Sol., Office of the Sol., of Arlington, Va., argued for appellee. With him on the brief were Fred E. McKelvey, Sol. and Richard E. Schafer, Associate Sol.

Before RICH, ARCHER, and MAYER, Circuit Judges.

RICH, Circuit Judge.

This appeal is from the September 12, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's rejection of claims 1-48 and 50-52 of application Serial No. 07/021,405, filed March 4, 1987, titled "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent" as unpatentable under 35 U.S.C. § 103, as well as the rejection of claims 1-48 and 50-51 under 35 U.S.C. § 112, first paragraph, for lack of enablement. We reverse the § 103 rejection. The § 112 rejection is affirmed in part and reversed in part.

## BACKGROUND

### A. The Invention

The claimed invention is directed to the use of genetic engineering techniques [FN1] for production of proteins that are toxic to insects such as larvae of mosquitos and black flies. These swamp-dwelling pests are the source of numerous human health problems, including malaria. It is known that certain species of the naturally-occurring *Bacillus* genus of bacteria produce proteins ("endotoxins") that are toxic to these insects. Prior art methods of combatting the insects involved spreading or spraying crystalline spores of the insecticidal *Bacillus* proteins over swamps. The spores were environmentally unstable, however, and would often sink to the bottom of a swamp before being consumed, thus rendering this method prohibitively expensive. Hence the need for a lower-cost method of producing the insecticidal *Bacillus* proteins in high volume, with application in a more stable vehicle.

[FN1] Basic vocabulary and techniques for gene cloning and expression have been described in *In re O'Farrell*, 853 F.2d 894, 895-99, 7 U.S.P.Q.2d 1673, 1674-77 (Fed.Cir.1988), and are not repeated here.

As described by appellants, the claimed subject matter meets this need by providing for the production of the insecticidal *Bacillus* proteins within host cyanobacteria. Although both cyanobacteria and bacteria are members of the procaryote [FN2] kingdom, the cyanobacteria (which in the past have been referred to as "blue-green algae") are unique among procaryotes in that the cyanobacteria are capable of oxygenic photosynthesis. The cyanobacteria grow on top of swamps where they are consumed by mosquitos and black flies. Thus, when *Bacillus* proteins are produced within \*490 transformed [FN3] cyanobacterial hosts according to the claimed invention, the presence of the insecticide in the food of the targeted insects advantageously guarantees direct uptake by the insects.

[FN2] All living cells can be classified into one of two broad groups, procaryotes and eucaryotes. The procaryotes comprise organisms formed of cells that do not have a distinct nucleus; their DNA floats throughout the cellular cytoplasm. In contrast, the cells of eucaryotic organisms such as man, other animals, plants, protozoa, algae and yeast have a distinct nucleus wherein their DNA resides.

[FN3] "Transformed" cyanobacteria are those that have successfully taken up the foreign *Bacillus* DNA such that the DNA information has become a permanent part of the host cyanobacteria, to be replicated as new cyanobacteria are generated.

More particularly, the subject matter of the application on appeal includes a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing [FN4] the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.

FN4. "Expression" of a gene refers to the production of the protein which the gene encodes; more specifically, it is the process of transferring information from a gene (which consists of DNA) via messenger RNA to ribosomes where a specific protein is made.

The claims on appeal are 1-48 and 50-52, all claims remaining in the application. Claim 1 reads:

1. A chimeric gene capable of being expressed in Cyanobacteria cells comprising:
  - (a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and
  - (b) at least one DNA fragment coding for an insecticidally active protein produced by a *Bacillus* strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein,

the DNA fragments being linked so that the gene is expressed.

Claims 2-15, which depend from claim 1, recite preferred *Bacillus* species, promoters, and selectable markers. [FN5] Independent claim 16 and claims 17-31 which depend therefrom are directed to a hybrid plasmid vector which includes the chimeric gene of claim 1. Claim 32 recites a bacterial strain. Independent claim 33 and claims 34-48 which depend therefrom recite a cyanobacterium which expresses the chimeric gene of claim 1. Claims 50-51 recite an insecticidal composition. Claim 52 recites a particular plasmid that appellants have deposited.

FN5. In the context of the claimed invention, "selectable markers" or "marker genes" refer to antibiotic-resistance conferring DNA fragments, attached to the gene being expressed, which facilitate the selection of successfully transformed cyanobacteria.

#### *B. Appellants' Disclosure*

In addition to describing the claimed invention in generic terms, appellants' specification discloses two particular species of *Bacillus* (*B. thuringiensis*, *B. sphaericus*) as

sources of insecticidal protein; and nine genera of cyanobacteria (*Synechocystis*, *Anacyclis*, *Synechococcus*, *Agmenellum*, *Aphanocapsa*, *Gloecapsa*, *Nostoc*, *Anabaena* and *Fremyella*) as useful hosts.

The working examples relevant to the claims on appeal detail the transformation of a single strain of cyanobacteria, i.e., *Synechocystis* 6803. In one example, *Synechocystis* 6803 cells are transformed with a plasmid comprising (1) a gene encoding a particular insecticidal protein ("B.t. 8") from *Bacillus thuringiensis* var. *israelensis*, linked to (2) a particular promoter, the  $P_L$  promoter from the bacteriophage Lambda (a virus of *E. coli*). In another example, a different promoter, i.e., the *Synechocystis* 6803 promoter for the rubisco operon, is utilized instead of the Lambda  $P_L$  promoter.

#### *C. The Prior Art*

A total of eleven prior art references were cited and applied, in various combinations, against the claims on appeal.

The focus of Dzelzkalns, [FN6] the primary reference cited against all of the rejected claims, is to determine whether chloroplast promoter sequences can function in cyanobacteria. To that end Dzelzkalns discloses the expression in cyanobacteria of a chimeric gene comprising a chloroplast promoter\*491 sequence fused to a gene encoding the enzyme chloramphenicol acetyl transferase (CAT). [FN7] Importantly, Dzelzkalns teaches the use of the CAT gene as a "marker" gene; this use of antibiotic resistance-conferring genes for selection purposes is a common technique in genetic engineering.

FN6. 12 *Nucleic Acids Res.* 8917 (1984).

FN7. Chloramphenicol is an antibiotic; CAT is an enzyme which destroys chloramphenicol and thus imparts resistance thereto.

Sekar I, [FN8] Sekar II, [FN9] and Ganesan [FN10] collectively disclose expression of genes encoding certain *Bacillus* insecticidal proteins in the bacterial hosts *B. megaterium*, *B. subtilis* and *E. coli*.

FN8. 137 *Biochem. and Biophys. Res. Comm.* 748

(1986).

FN9. 33 *Gene* 151 (1985).

FN10. 189 *Mol. Gen. Genet.* 181 (1983).

Friedberg [FN11] discloses the transformation of the cyanobacterium *Anacystis nidulans* R2 by a plasmid vector comprising the O<sub>L</sub>P<sub>L</sub> operator-promoter region and a temperature-sensitive repressor gene of the bacteriophage Lambda. While the cyanobacteria are attractive organisms for the cloning of genes involved in photosynthesis, Friedberg states, problems may still be encountered such as suboptimal expression of the cloned gene, detrimental effects on cell growth of overexpressed, highly hydrophobic proteins, and rapid turnover of some gene products. To address these problems, Friedberg teaches the use of the disclosed Lambda regulatory signals in plasmid vehicles which, it states, have "considerable potential for use as vectors the expression of which can be controlled in *Anacystis*...."

FN11. 203 *Mol. Gen. Genet.* 505 (1986).

Miller [FN12] compares the initiation specificities *in vitro* of DNA-dependent RNA polymerases [FN13] purified from two different species of cyanobacteria (*Fremyella diplosiphon* and *Anacystis nidulans*), as well as from *E. coli*.

FN12. 140 *J. Bacteriology* 246 (1979).

FN13. RNA polymerase, the enzyme responsible for making RNA from DNA, binds at specific nucleotide sequences (promoters) in front of genes in DNA, and then moves through the gene making an RNA molecule that includes the information contained in the gene. Initiation specificity is the ability of the RNA polymerase to initiate this process specifically at a site(s) on the DNA template.

Nierzwicki-Bauer [FN14] identifies in the cyanobacterium *Anabaena* 7120 the start site for transcription of the gene encoding *rbcL*, the large subunit of the enzyme ribulose-1,5-bisphosphate carboxylase. It reports that the

nucleotide sequence 14-8 base pairs preceding the transcription start site "resembles a good *Escherichia coli* promoter," but that the sequence 35 base pairs before the start site does not.

FN14. 81 *Proc. Natl. Acad. Sci. USA* 5961 (1984).

Chauvat [FN15] discloses host-vector systems for gene cloning in the cyanobacterium *Synechocystis* 6803, in which the antibiotic resistance-conferring *neo* gene is utilized as a selectable marker.

FN15. 204 *Mol. Gen. Genet.* 185 (1986).

Reiss [FN16] studies expression in *E. coli* of various proteins formed by fusion of certain foreign DNA sequences with the *neo* gene.

FN16. 30 *Gene* 211 (1984).

Kolowsky [FN17] discloses chimeric plasmids designed for transformation of the cyanobacterium *Synechococcus* R2, comprising an antibiotic-resistant gene linked to chromosomal DNA from the *Synechococcus* cyanobacterium.

FN17. 27 *Gene* 289 (1984).

Barnes, United States Patent No. 4,695,455, is directed to the treatment with stabilizing chemical reagents of pesticides produced by expression of heterologous genes (such as those encoding *Bacillus* proteins) in host microbial cells such as *Pseudomonas* bacteria. The host cells are killed by this treatment, but the resulting pesticidal compositions exhibit prolonged toxic activity when exposed to the environment of target pests.

#### \*492 D. The Grounds of Rejection

##### 1. The § 103 Rejections

Claims 1-6, 16-21, 33-38, 47-48 and 52 (which include all independent claims in the application) were rejected as unpatentable under 35 U.S.C. § 103 based upon Dzelzkalns in view of Sekar I or Sekar II and Ganesan. The examiner stated that Dzelzkalns discloses a chimeric gene capable of

being highly expressed in a cyanobacterium, said gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding CAT. The examiner acknowledged that the chimeric gene and transformed host of Dzelzkalns differ from the claimed invention in that the former's structural gene encodes CAT rather than insecticidally active protein. However, the examiner pointed out, Sekar I, Sekar II, and Ganesan teach genes encoding insecticidally active proteins produced by *Bacillus*, and the advantages of expressing such genes in heterologous [FN18] hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus* genes taught by Sekar I, Sekar II, and Ganesan for the CAT gene in the vectors of Dzelzkalns in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the expression of heterologous genes. In the absence of evidence to the contrary, the examiner contended, the invention as a whole was *prima facie* obvious.

FN18. Denotes different species or organism.

Additional rejections were entered against various groups of dependent claims which we need not address here. All additional rejections were made in view of Dzelzkalns in combination with Sekar I, Sekar II, and Ganesan, and further in view of other references discussed in Part C above.

The Board affirmed the § 103 rejections, basically adopting the examiner's Answer as its opinion while adding a few comments. The legal conclusion of obviousness does not require absolute certainty, the Board added, but only a reasonable expectation of success, citing *In re O'Farrell*, 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed.Cir.1988). In view of the disclosures of the prior art, the Board concluded, one of ordinary skill in the art would have been motivated by a reasonable expectation of success to make the substitution suggested by the examiner.

## 2. The § 112 Rejection

The examiner also rejected claims 1-48 and 50-51 under 35 U.S.C. § 112, first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. Citing *Manual of Patent Examining Procedure* (MPEP) provisions 706.03(n) [FN19] and (z) [FN20] as support, the examiner took the position that undue experimentation would be required of the art worker to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided \*493 in the specification. With respect to unpredictability, the examiner stated that

FN19. MPEP 706.03(n), "Correspondence of Claim and Disclosure," provides in part:

In chemical cases, a claim may be so broad as to not be supported by [the] disclosure, in which case it is rejected as unwarranted by the disclosure....

FN20. MPEP 706.03(z), "Undue Breadth," provides in part:

[I]n applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Sol*, 1938 C.D. 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield*, 1940 C.D. 351; 518 O.G. 255 gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." ...

[t]he cyanobacteria comprise a large and diverse group of photosynthetic bacteria including large numbers of species in some 150 different genera including *Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*,

*Nostoc*, *Anabaena*, etc. The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse and relatively poorly studied group of prokaryotes is high....

The Board affirmed, noting that "the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in this particular art, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. *In re Fisher*, 427 F.2d 833, 166 U.S.P.Q. 18 (CCPA 1970)."

#### OPINION

##### A. Obviousness

[1] We first address whether the PTO erred in rejecting the claims on appeal as *prima facie* obvious within the meaning of 35 U.S.C. § 103. Obviousness is a legal question which this court independently reviews, though based upon underlying factual findings which we review under the clearly erroneous standard. *In re Woodruff*, 919 F.2d 1575, 1577, 16 U.S.P.Q.2d 1934, 1935 (Fed.Cir.1990).

[2] Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir.1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

[3] We agree with appellants that the PTO has not established the *prima facie* obviousness of the claimed subject matter. The prior art simply does not disclose or suggest the expression in cyanobacteria of a chimeric gene encoding an insecticidally active protein, or convey to those

of ordinary skill a reasonable expectation of success in doing so. More particularly, there is no suggestion in Dzelzkalns, the primary reference cited against all claims, of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. The expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes.

The PTO argues that the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria is suggested by the secondary references Sekar I, Sekar II, and Ganesan, which collectively disclose expression of genes encoding *Bacillus* insecticidal proteins in two species of host *Bacillus* bacteria (*B. megaterium* and *B. subtilis*) as well as in the bacterium *E. coli*. While these references disclose expression of *Bacillus* genes encoding insecticidal proteins in certain transformed *bacterial* hosts, nowhere do these references disclose or suggest expression of such genes in transformed *cyanobacterial* hosts.

To remedy this deficiency, the PTO emphasizes similarity between bacteria and cyanobacteria, namely, that these are both prokaryotic organisms, and argues that this fact would suggest to those of ordinary skill the use of cyanobacteria as hosts for expression of the claimed chimeric genes. While it is true that bacteria and cyanobacteria are now both classified as prokaryotes, that fact alone is not sufficient to motivate the art worker as the PTO contends. \*494 As the PTO concedes, cyanobacteria and bacteria are not identical; they are classified as two separate divisions of the kingdom Prokaryotae. [FN21] Moreover, it is only in recent years that the biology of cyanobacteria has been clarified, as evidenced by references in the prior art to "blue-green algae." Such evidence of recent uncertainty regarding the biology of cyanobacteria tends to rebut, rather than support, the PTO's position that one would consider the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.

[FN21] *Stedman's Medical Dictionary* 1139 (24th ed. 1982) (definition of "Prokaryotae"). Prokaryotic organisms are commonly classified according to the following taxonomic hierarchy: Kingdom;

Division; Class; Order; Family; Genus; Species. 3  
*Bergey's Manual of Systematic Bacteriology* 1601  
 (1989).

At oral argument the PTO referred to additional secondary references, not cited against any independent claim (i.e., Friedberg, Miller, and Nierzwicki-Bauer), which it contended disclose certain amino acid sequence homology between bacteria and cyanobacteria. The PTO argued that such homology is a further suggestion to one of ordinary skill to attempt the claimed invention. We disagree. As with the Dzelzkalns, Sekar I, Sekar II, and Ganesan references discussed above, none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. In fact, these additional references suggest as much about *differences* between cyanobacteria and bacteria as they do about similarities. For example, Nierzwicki-Bauer reports that a certain nucleotide sequence (i.e., the -10 consensus sequence) in a particular cyanobacterium resembles an *E. coli* promoter, but that another nearby nucleotide sequence (the -35 region) does not. While Miller speaks of certain promoters of the bacteriophage Lambda that are recognized by both cyanobacterial and *E. coli* RNA polymerases, it also discloses that these promoters exhibited differing strengths when exposed to the different polymerases. Differing sensitivities of the respective polymerases to an inhibitor are also disclosed, suggesting differences in the structures of the initiation complexes.

The PTO asks us to agree that the prior art would lead those of ordinary skill to conclude that cyanobacteria are attractive hosts for expression of any and all heterologous genes. Again, we can not. The relevant prior art does indicate that cyanobacteria are attractive hosts for expression of both native and heterologous *genes involved in photosynthesis* (not surprisingly, for the capability of undergoing oxygenic photosynthesis is what makes the cyanobacteria unique among prokaryotes). However, these references do not suggest that cyanobacteria would be equally attractive hosts for expression of *unrelated* heterologous genes, such as the claimed genes encoding *Bacillus* insecticidal proteins.

In *O'Farrell*, this court affirmed an obviousness rejection of

a claim to a method for producing a "predetermined protein in a stable form" in a transformed bacterial host. 853 F.2d at 895, 7 U.S.P.Q.2d at 1674. The cited references included a prior art publication (the Polisky reference) whose three authors included two of the three coinventor-appellants. The main difference between the prior art and the claim at issue was that in Polisky, the heterologous gene was a gene for ribosomal RNA, while the claimed invention substituted a gene coding for a predetermined protein. Id. at 901, 7 U.S.P.Q.2d at 1679. Although, as the appellants therein pointed out, the ribosomal RNA gene is not normally translated into protein, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein, and further predicted that if a gene coding for a protein were to be substituted, extensive translation might result. *Id.* We thus affirmed, explaining that

the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the [claimed] method could be used to make proteins.  
 ....

**\*495** ... Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.

Id. at 901-02, 7 U.S.P.Q.2d at 1679-80.

In contrast with the situation in *O'Farrell*, the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art. Moreover, the "reasonable expectation of success" that was present in *O'Farrell* is not present here. Accordingly, we reverse the § 103 rejections.

#### *B. Enablement*

[4] The first paragraph of 35 U.S.C. § 112 requires, *inter alia*, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed.Cir.1988). That *some*

experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." *Id.* at 736-37, 8 U.S.P.Q.2d at 1404. Enablement, like obviousness, is a question of law which we independently review, although based upon underlying factual findings which we review for clear error. See *id.* at 735, 8 U.S.P.Q.2d at 1402.

[5] In response to the § 112 rejection, appellants assert that their invention is "pioneering," and that this should entitle them to claims of broad scope. Narrower claims would provide no real protection, appellants argue, because the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in their specification, appellants contend that any skilled microbiologist could construct vectors and transform many different cyanobacteria, using a variety of promoters and *Bacillus* DNA, and could easily determine whether or not the active *Bacillus* protein was successfully expressed by the cyanobacteria.

The PTO made no finding on whether the claimed invention is indeed "pioneering," and we need not address the issue here. With the exception of claims 47 and 48, the claims rejected under § 112 are not limited to any particular genus or species of cyanobacteria. The PTO's position is that the cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising some 150 different genera, and that heterologous gene expression in cyanobacteria is "unpredictable." Appellants have not effectively disputed these assertions. Moreover, we note that only one particular species of cyanobacteria is employed in the working examples of appellants' specification, and only nine genera of cyanobacteria are mentioned in the entire document.

Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of particular cyanobacterial genera operative in the claimed invention, we are not persuaded that the PTO erred in rejecting claims 1-46 and 50-51 under § 112, first paragraph. There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. See *In re Fisher*, 427 F.2d 833, 839,

166 U.S.P.Q. 18, 24 (CCPA 1970) (the first paragraph of § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification). [FN22] Accordingly, \*496 we affirm the § 112 rejection as to those claims.

[FN22] The enablement rejection in this case was not based upon a post-filing date state of the art, as in *In re Hogan*, 559 F.2d 595, 605- 07, 194 U.S.P.Q. 527, 536-38 (CCPA 1977). See also *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed.Cir.1989) (citing *Hogan*); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1568-69, 15 U.S.P.Q.2d 1039, 1047-48 (Fed.Cir.1990) (directing district court, on remand, to consider effect of *Hogan* and *United States Steel* on the enablement analysis of *Fisher*), cert. dismissed, 499 U.S. 955, 111 S.Ct. 1434, 113 L.Ed.2d 485 (1991). We therefore do not consider the effect of *Hogan* and its progeny on *Fisher*'s analysis of when an inventor should be allowed to "dominate the future patentable inventions of others." *Fisher*, 427 F.2d at 839, 166 U.S.P.Q. at 24.

[6] In so doing we do not imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, [FN23] to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for

example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. See *Fisher*, 427 F.2d at 839, 166 U.S.P.Q. at 24. In this case, we agree with the PTO that appellants' limited disclosure does not enable one of ordinary skill to make and use the invention as now recited in claims 1-46 and 50-51 without undue experimentation.

**FN23.** The first paragraph of § 112 requires nothing more than *objective* enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (CCPA 1971). How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant. *Id.*

Remaining dependent claim 47 recites a cyanobacterium which expresses the chimeric gene of claim 1, wherein the cyanobacterium is selected from among the genera *Anacystis* and *Synechocystis*. Claim 48, which depends from claim 47, is limited to the cyanobacterium *Synechocystis* 6803. The PTO did not separately address these claims, nor indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria. Although these claims are not limited to expression of genes encoding particular *Bacillus* proteins, we note what appears to be an extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects. The rejection of claims 47-48 under § 112 will not be sustained.

#### CONCLUSION

The rejection of claims 1-48 and 50-52 under 35 U.S.C. § 103 is *reversed*. The rejection of claims 1-46 and 50-51 under 35 U.S.C. § 112, first paragraph, is *affirmed* and the rejection of claims 47 and 48 thereunder is *reversed*.

AFFIRMED-IN-PART, REVERSED-IN-PART.

MAYER, Circuit Judge, dissenting.

An appeal is not a second opportunity to try a case or prosecute a patent application, and we should not allow parties to "undertake to retry the entire case on appeal." *Perini America, Inc. v. Paper Converting Machine Co.*, 832 F.2d 581, 584, 4 U.S.P.Q.2d 1621, 1624 (Fed.Cir.1987);

*Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 877, 229 U.S.P.Q. 668, 671 (Fed.Cir.1986). But that is precisely what the court has permitted here. The PTO conducted a thorough examination of the prior art surrounding this patent application and concluded the claims would have been obvious. The board's decision based on the examiner's answer which comprehensively explains the rejection is persuasive and shows how the evidence supports the legal conclusion that the claims would have been obvious. Yet, the court ignores all this and conducts its own examination, if you will, as though the examiner and board did not exist. Even if I thought this opinion were more persuasive than the board's, I could \*497 not join it because it misperceives the role of the court.

The scope and content of the prior art, the similarity between the prior art and the claims, the level of ordinary skill in the art, and what the prior art teaches are all questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 693-94, 15 L.Ed.2d 545, 148 U.S.P.Q. 459, 467 (1966); *Jurgens v. McKasy*, 927 F.2d 1552, 1560, 18 U.S.P.Q.2d 1031, 1037 (Fed.Cir.1991). And "[w]here there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574, 105 S.Ct. 1504, 1511-12, 84 L.Ed.2d 518 (1985). The mere denomination of obviousness as a question of law does not give the court license to decide the factual matters afresh and ignore the requirement that they be respected unless clearly erroneous. *In re Woodruff*, 919 F.2d 1575, 1577, 16 U.S.P.Q.2d 1934, 1935 (Fed.Cir.1990); *In re Kulling*, 897 F.2d 1147, 1149, 14 U.S.P.Q.2d 1056, 1057 (Fed.Cir.1990). There may be more than one way to look at the prior art, but on this record we are bound by the PTO's interpretation of the evidence because it is not clearly erroneous and its conclusion is unassailable. I would affirm on that basis.

947 F.2d 488, 20 U.S.P.Q.2d 1438

END OF DOCUMENT

**Briefs and Other Related Documents**

United States Court of Appeals,  
 Federal Circuit.

MEHL/BIOPHILE INTERNATIONAL CORP., Selvac  
 Acquisitions Corp. and Nardo Zaias,  
 M.D., Plaintiffs-Appellants,

v.

Sandy MILGRAUM, M.D., Palomar Medical Technologies,  
 Inc., and Spectrum Medical  
 Technologies, Inc., Defendants-Appellees.  
**No. 99-1038.**

Sept. 30, 1999.

Rehearing Denied Oct. 27, 1999.

Patentee brought action for infringement of patent claiming method of hair removal using laser. The United States District Court for the District of New Jersey, Alfred M. Wolin, J., 8 F.Supp.2d 434, granted summary judgment of invalidity, and patentee appealed. The Court of Appeals, Rader, Circuit Judge, held that: (1) patent was not anticipated by instruction manual for laser used to remove tattoos, but (2) patent was anticipated by prior art article.

Affirmed.

West Headnotes

**[1] Patents** 72(1)**291k72(1) Most Cited Cases**

To anticipate a patent claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.

**[2] Patents** 72(1)**291k72(1) Most Cited Cases**

Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the limitations claimed in a patent, it anticipates.

**[3] Patents** 65**291k65 Most Cited Cases**

Inherency of patent claim's limitations in a prior art reference, for anticipation purposes, is not necessarily

coterminous with the knowledge of those of ordinary skill in the art; artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.

**[4] Patents** 67.1**291k67.1 Most Cited Cases**

Patented method of removing hair by using a laser was not anticipated by instruction manual for laser used to remove tattoos, since manual did not include limitation of aligning laser over a hair follicle opening, and such alignment was not inherent in manual's disclosure, notwithstanding possibility of such alignment.

**[5] Patents** 72(1)**291k72(1) Most Cited Cases**

Occasional results are not inherent, for purpose of determining whether patent is anticipated by prior art alleged to inherently include claimed limitations.

**[6] Federal Courts** 762**170Bk762 Most Cited Cases**

Appellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record.

**[7] Patents** 70**291k70 Most Cited Cases**

Patented method of removing hair by using a laser was anticipated by prior art article documenting study of tissue damage induced by laser pulses on epilated backs of guinea pigs, which showed that natural result flowing from the operation as taught would result in alignment of the laser light over a hair follicle, as claimed in the patent, notwithstanding fact that study involved guinea pigs or that article failed to mention hair depilation as a goal.

**Patents** 328(2)**291k328(2) Most Cited Cases****5,059,192. Invalid.**

\*1363 Jeffrey A. Schwab, Abelman, Frayne & Schwab, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Michael Aschen and Anthony J. DiFilippi. Of counsel on the brief was George A. Arkwright, Schlesinger, Arkwright & Garvey, LLP, of Arlington, Virginia.

Wayne L. Stoner, Hale and Dorr, LLP, of Boston, Massachusetts, argued for defendants-appellees. With him on the brief were William F. Lee and James M. Hall. Of counsel on the brief was Thomas A. Reed, Palomar Medical Technologies, Inc., of Lexington, Massachusetts.

Before MAYER, MICHEL, and RADER, Circuit Judges.

RADER, Circuit Judge.

In this patent infringement action, MEHL/Biophile International Corp., Selvac Acquisitions Corp., and Dr. Nardo Zaias (collectively, MEHL/Biophile) asserted that Dr. Sandy Milgraum, Palomar Medical Technologies, Inc., and Spectrum Medical Technologies, Inc. (Milgraum) infringed U.S. Patent No. 5,059,192 (the '192 patent). On its motion for summary judgment, Milgraum contended that all of the '192 patent claims were anticipated by an instruction manual for the Spectrum RD-1200 laser and by a 1987 Journal of Investigative Dermatology article authored by Dr. Luigi Polla and others (the Polla article). The district court agreed that the manual anticipated the claims, granted summary judgment of invalidity, and dismissed the action. See \*1364Mehl/Biophile Int'l Corp. v. Milgraum, 8 F.Supp.2d 434, 47 USPQ2d 1248 (D.N.J.1998). Although this court disagrees that the manual discloses all the elements of the claimed invention, because the Polla article does, this court affirms.

I.

The '192 patent, entitled "Method of Hair Depilation," claims a method for removing hair using a laser. Hairs grows out of hair follicles, tubular apertures in the skin. The collection of germ cells from which hairs grow, known as the papilla, lies at the base of the follicle. The '192 patent claims a method for destroying the papilla, thereby preventing hair regrowth. The written description discloses the use of a Q-switched ruby laser to effect the destruction.

At a meeting of the American Academy of Dermatology, Dr. Zaias visited Spectrum's booth where Spectrum displayed such a laser, known as the RD-1200. Spectrum sold the RD-1200 for use in removing tattoos. Dr. Zaias recognized that the same principles that govern laser absorption in skin pigmented by a tattoo would also focus

laser absorption on the natural skin pigment found in the papilla. More specifically, the papilla contains granules (called melanosomes) of a dark pigment (called melanin). A Q-switched ruby laser aimed at the hair follicle will penetrate the skin and reach the papillary melanin. At a particular wavelength, the laser will heat up and destroy the papilla without damaging surrounding tissue.

Claim 1 of the patent, the only independent claim, reads:

1. A method of hair depilation, comprising the steps of:
  - a) aligning a laser light applicator substantially vertically over a hair follicle opening, said applicator having an aperture of sufficient area to surround a hair follicle and overlie its papilla;
  - b) applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a radiant exposure dose of sufficient energy and duration to damage its papilla so that hair regrowth is prevented and scarring of the surrounding skin is avoided.

Dependent claims 2-6 further specify parameters of the laser light applicator, energy delivery, and the type of laser.

MEHL/Biophile sued Milgraum in the United States District Court for the District of New Jersey for infringement of all the claims of the '192 patent. Milgraum moved for summary judgment of invalidity based on 35 U.S.C. § 102 (1994), arguing that two prior art references each teach all the limitations of the claims. As noted at the outset, Milgraum relied on the manual for the RD-1200 laser which describes the use of a laser to remove tattoos. The manual teaches the use of a Q-switched ruby laser to remove a tattoo: "[E]nergy is selectively absorbed only by pigmented chromophores and not surrounding tissue, greatly reducing the risk of scarring."

Milgraum also relied on the Polla article entitled "Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin." The Polla article documents "the tissue damage induced by Q-switched ruby laser pulses in black, brown, and albino (control) guinea pigs ... in an effort to define the nature and extent of pigmented cell injury." The method involves epilating guinea pigs with soft wax, holding the aperture of the laser in contact with the skin, and pulsing the laser. Using an

electron microscope, the researchers observed "disruption of melanosomes deep in the hair papillae."

The district court considered both references, but ultimately rested its decision on the RD-1200 manual. MEHL/Biophile appeals. MEHL/Biophile makes several arguments for disregarding the manual as an anticipating reference. For instance, MEHL/Biophile argues that the manual does not teach use of the laser to remove hair at all. Further MEHL/Biophile contends that the manual does not disclose a substantially vertical alignment, a claim element. As for the Polla article, \*1365 MEHL/Biophile argues that the reference relates to guinea pig skin and does not mention hair depilation. In addition, MEHL/Biophile contends that the epilation of the guinea pig backs removed the papilla so the laser treatment could not have damaged the papilla.

## II.

This court reviews a district court's grant of summary judgment by reapplying the standard applicable at the district court. See *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed.Cir.1994).

Summary judgment is appropriate only when "there is no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). In its review, this court draws all reasonable inferences in favor of the non-movant. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

[1][2][3] "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed.Cir.1997). As this court's predecessor stated in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 USPO 665, 667 (1939)) (internal citations omitted):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure

should be regarded as sufficient.

Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *In re Oelrich*, 666 F.2d at 581; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051, 1053 (Fed.Cir.1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed.Cir.1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* 801 F.2d at 1326.

### The RD-1200 Manual

[4] The RD-1200 manual cannot anticipate because it does not teach all the limitations of the claimed invention. Claim 1 includes the step of "aligning a laser light applicator substantially vertically over a hair follicle opening." The parties agree that the manual does not discuss hair follicles, let alone aligning the laser over a hair follicle opening. Thus, the manual does not explicitly teach alignment substantially vertically over a follicle opening. Without explicit teachings of this claim limitation, this court must nonetheless examine whether such alignment is inherent in the manual's disclosure.

[5] The manual teaches aiming the laser at skin pigmented with tattoo ink. The record discloses no necessary relationship between the location of a tattoo and the location of hair follicles. Therefore, an operator of the RD-1200 laser could use the laser according to the manual without necessarily aligning the laser "substantially vertically over a hair follicle opening." The possibility of such an alignment does not legally suffice to show anticipation. See *In re Oelrich*, 666 F.2d at 581. Occasional results are not inherent. Because this court holds that the manual does not inherently teach this limitation of the claimed invention, it does not address MEHL/Biophile's other arguments. To anticipate, a single reference must teach every limitation of the claimed invention. Without an inherent teaching about alignment, the manual does not anticipate the claimed

invention.

**\*1366 The Polla Article**

[6] Although the district court did not reach the Polla article in its anticipation analysis, "[a]ppellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record." *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 822 n. 1, 11 USPQ2d 1321, 1322 n. 1 (Fed.Cir.1989). Milgram asserts that the Polla article constitutes such an alternative ground. This court agrees.

[7] As to the "aligning" step, the Polla article does not suffer from the same deficiency as the manual. It is not a question of probabilities as to whether a person of ordinary skill following the teachings of the article will align the laser light applicator over a hair follicle. The researchers focused their study on the epilated backs of guinea pigs. No one disputes that guinea pigs have hairy backs. Indeed, the article itself is replete with references to the irradiation of hair follicles and resulting follicular damage:

At 0.8 J/cm<sup>2</sup>, epidermal lesions were more marked and involved hair follicles 0.3 mm below the skin surface.... [L]esions were also present 0.5 mm deep in follicles.

[E]ven at the highest radiant exposure (1.2 J/cm<sup>2</sup>), brown [guinea pig] skin never showed full-thickness epidermal necrosis and at 0.8 J/cm<sup>2</sup>, follicular damage was observed to a depth of 0.5 mm and at 1.2 J/cm<sup>2</sup> to a depth of 0.7 mm below the skin surface.

Follicular changes were similar in nature and extent to the epidermal alterations described above, and were associated with melanosome disruption.

Specifically, we have shown that ... pigmented structures in the deep dermis such as hair follicles are affected....

The article further contains a photograph showing "[f]ollicular changes induced by ruby laser." The changes include disruption of "melanosomes contained within follicular epithelium." Moreover the article specifically mentioned disruption of the hair papillae:

At 0.8 and 1.2 J/cm<sup>2</sup>, individual melanosomes were more intensely damaged and disruption of melanosomes deep

in the hair papillae was observed.

Finally, the method of exposing the Q-switched ruby laser to the guinea pig skin also inherently teaches substantially vertical alignment over hair follicle openings:

The collimated laser beam struck a circular aperture, 2.5 mm in diameter, held in contact with the skin of the animals.

The record shows that holding the collimated laser in contact with the skin would align it perpendicular to the skin surface and therefore substantially vertically over follicle openings. Viewed as a whole, this disclosure shows, in the words of *In re Oelrich*, 666 F.2d at 581, that the "natural result flowing from the operation as taught would result in" alignment of the laser light over a hair follicle, as claimed. No reasonable jury could find otherwise.

MEHL/Biophile's remaining arguments concerning the Polla article are unavailing. The Polla article concerns itself with guinea pig, rather than human, skin, but that difference is irrelevant to the anticipation analysis. Nothing in the claim limits the method's reach to human skin. Similarly, the Polla article's failure to mention hair depilation as a goal is similarly irrelevant. MEHL/Biophile does not dispute on appeal that the laser operating parameters disclosed in the article substantially coincide with those disclosed in the patent. Accordingly, to the extent the embodiment in the patent achieves hair depilation, so does the Polla method. Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results. See *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed.Cir.1983). Finally, as mentioned earlier, the article itself belies MEHL/Biophile's argument that the wax epilation prescribed by the article resulted in removal of the papilla. \*1367 The article specifically states that "disruption of melanosomes deep in the hair papillae was observed." MEHL/Biophile's expert testimony contradicting the plain language of the reference does not create a genuine issue of fact.

Thus, the Polla article anticipates claim 1 of the '192 patent. Because MEHL/Biophile has not separately argued the validity of the dependent claims, the judgment of invalidity as to those claims also stands.

COSTS

Each party shall bear its own costs.

*AFFIRMED*

192 F.3d 1362, 52 U.S.P.Q.2d 1303

**Briefs and Other Related Documents ([Back to top](#))**

- [1999 WL 33918087](#) (Appellate Petition, Motion and Filing) Petition for Rehearing (Oct. 14, 1999)Original Image of this Document with Appendix (PDF)
- [1999 WL 33614426](#) (Appellate Brief) Reply Brief of Plaintiffs-Appellants (Apr. 06, 1999)Original Image of this Document (PDF)
- [1999 WL 33614425](#) (Appellate Brief) Brief of Defendants-Appellees (Mar. 01, 1999)Original Image of this Document (PDF)
- [99-1038](#) (Docket) (Oct. 29, 1998)
- [1998 WL 34082809](#) (Appellate Brief) Brief of Plaintiffs-Appellants (Jan. 04, 1998)Original Image of this Document with Appendix (PDF)

END OF DOCUMENT

**Briefs and Other Related Documents**

United States Court of Appeals,  
Federal Circuit.

In re Anita DEMBICZAK and Benson Zinbarg, Appellants.  
**No. 98-1498.**

April 28, 1999.

Board of Patent Appeals and Interferences upheld rejection of application for utility patent, and appeal was taken. The United States Court of Appeals for the Federal Circuit, Clevenger, Circuit Judge, held that: (1) Board erred by rejecting application for patent on plastic trash bags with pumpkin face on grounds of obviousness, without finding suggestion, teaching, or motivation to combine prior art references, and (2) applicant's earlier design patents involving pumpkin faces on bags did not preclude issuance of patent in present case, under obviousness-type double patenting doctrine.

Reversed.

## West Headnotes

**[1] Patents** **113(6)****291k113(6) Most Cited Cases**

Federal Circuit determines legal question of obviousness of patent without deference to Board of Patent Appeals and Interferences, and examines any factual findings for clear error. 35 U.S.C.A. § 103(a).

**[2] Patents** **16(1)****291k16(1) Most Cited Cases**

Measuring a claimed invention for obviousness requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. 35 U.S.C.A. § 103(a).

**[3] Patents** **16(4)****291k16(4) Most Cited Cases**

Best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis of a patent application

is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

35 U.S.C.A. § 103(a).

**[4] Patents** **26(1)****291k26(1) Most Cited Cases**

Evidence of a suggestion, teaching, or motivation to combine prior art references, sufficient to render invention obvious and unpatentable, may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. 35 U.S.C.A. § 103(a).

**[5] Patents** **36(1)****291k36(1) Most Cited Cases**

Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence sufficient to render invention obvious and unpatentable. 35 U.S.C.A. § 103(a).

**[6] Patents** **16.27****291k16.27 Most Cited Cases**

Board of Patent Appeals and Interferences erred by denying for obviousness

application for utility patent for orange colored plastic trash bag with markings, which expanded to show face of pumpkin when filled with leaves, when Board cited prior art showing placement of pumpkin faces on crepe paper and which disclosed features of plastic trash bags and concluded that prior art references collectively described all limitations of present claims; Board should have found a suggestion, teaching, or motivation to combine prior art references. 35 U.S.C.A. § 103(a).

**[7] Patents** **113(6)****291k113(6) Most Cited Cases**

Federal Circuit would not consider argument made in support of obviousness of patent application, which was not raised before Board of Patent Appeals and Interferences. 35 U.S.C.A. § 103(a).

**[8] Patents** **120****291k120 Most Cited Cases**

The doctrine of "obviousness-type double patenting" prohibits claims in a second patent which define merely an obvious variation of an invention claimed by the same

inventor in an earlier patent. 35 U.S.C.A. § 103(a).

#### [9] Patents ~~314(5)~~ 314(5)

##### 291k314(5) Most Cited Cases

Question whether patent application is to be rejected, under obvious-type double patenting doctrine, on grounds that claimed invention was merely an obvious variation on invention disclosed in existing patent, is one of law, which Federal Circuit reviews de novo. 35 U.S.C.A. § 103(a).

#### [10] Patents ~~3120~~ 3120

##### 291k120 Most Cited Cases

In some very rare cases, obvious-type double patenting, in which invention claimed in patent application was obvious variation on invention disclosed by existing patent, may be found between design and utility patents. 35 U.S.C.A. § 103(a).

#### [11] Patents ~~3120~~ 3120

##### 291k120 Most Cited Cases

When utility patent is sought to be invalidated due to obviousness, in light of previous design patents, rejection under obviousness-type double patenting doctrine is appropriate only if the claims of the two patents cross-read, meaning that the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the other patent, and vice versa. 35 U.S.C.A. § 103(a).

#### [12] Patents ~~3128~~ 3128

##### 291k28 Most Cited Cases

In order for a design to be unpatentable because of obviousness, there must first be a basic design reference in the prior art, the design characteristics of which are basically the same as the claimed design. 35 U.S.C.A. § 103(a).

#### [13] Patents ~~3120~~ 3120

##### 291k120 Most Cited Cases

Phrase "having facial indicia thereon," contained in claim of application for utility patent on plastic trash bag with pumpkin face, was not design reference that was basically the same as claimed design covered by design patents on jack-o-lantern faces on bags, and application was consequently not required to be rejected under obviousness-type double patenting doctrine. 35 U.S.C.A. §

103(a).

\*996 David P. Gordon, of Stamford, Connecticut, argued for appellant. Of counsel was Thomas A. Gallagher, of Stamford, Connecticut.

John M. Whealan, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief were Albin F. Drost, Acting Solicitor, and David R. Nicholson, Associate Solicitor.

Before MAYER, Chief Judge, MICHEL and CLEVENGER, Circuit Judges.

CLEVENGER, Circuit Judge.

Anita Dembiczkak and Benson Zinbarg appeal the rejection, upheld by the Board of Patent Appeals and Interferences, of all pending claims in their Application No. 08/427,732. See *Ex Parte Dembiczkak*, No. 96-2648, slip op. at 43 (May 14, 1998). Because the Board erred in sustaining rejections of the pending claims as obvious under 35 U.S.C. § 103(a) (Supp.1998), and for obviousness-type double patenting, we reverse.

## I

The invention at issue in this case is, generally speaking, a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern. As the inventors, Anita Dembiczkak and Benson Zinbarg (collectively, "Dembiczkak") note, the invention solves the long-standing problem of unsightly trash bags placed on the curbs of America, and, by fortuitous happenstance, allows users to express their whimsical or festive nature while properly storing garbage, leaves, or other household debris awaiting collection. Embodiments of the invention--sold under a variety of names, including Giant Stuff-A-Pumpkin, Funkins, Jack Sak, and Bag-O-Fun--have undisputedly been well-received by consumers, who bought more than seven million units in 1990 alone. Indeed, in 1990, the popularity of the pumpkin bags engendered a rash of thefts around Houston, Texas, leading some owners to resort to preventative measures, such as greasing the bags with petroleum jelly and tying them to trees. See R. Piller, "Halloween Hopes Die on the

Vine," *Hous. Chron.*, Oct. 19, 1990, at 13A.

The road to profits has proved much easier than the path to patentability, however. In July 1989, Dembiczak filed a utility patent application generally directed to the pumpkin bags. In a February 1992 appeal, the Board of Patent Appeals and Interferences ("the Board") reversed the Examiner's rejection, but entered new grounds for rejection. Dembiczak elected to continue prosecution, filing a continuation application to address the new grounds for rejection. Thereafter, the invention made a second appearance before the Board, in April 1993, when the Board both sustained the Examiner's rejection and again entered new grounds for rejection. Again, a continuation application was filed (the instant application). And again the Examiner's rejection was appealed to the Board, which sustained the rejection in a May 14, 1998, decision. See *Dembiczak*, slip op. at 43.

#### A

The patent application at issue includes claims directed to various embodiments of \*997 the pumpkin bag. Claims 37, 49, 51, 52, 58 through 64, 66 through 69, and 72 through 81 are at issue in this appeal. Though the claims vary, independent claim 74 is perhaps most representative:

74. A decorative bag for use by a user with trash filling material, the bag simulating the general outer appearance of an outer surface of a pumpkin having facial indicia thereon, comprising:

a flexible waterproof plastic trash or leaf bag having an outer surface which is premanufactured orange in color for the user to simulate the general appearance of the outer skin of a pumpkin, and having facial indicia including at least two of an eye, a nose and a mouth on the orange color outer surface for forming a face pattern on said orange color outer surface to simulate the general outer appearance of a decorative pumpkin with a face thereon,

said trash or leaf bag having first and second opposite ends, at least said second end having an opening extending substantially across the full width of said trash or leaf bag for receiving the trash filling material,

wherein when said trash or leaf bag is filled with trash filling material and closed, said trash or leaf bag takes the

form and general appearance of a pumpkin with a face thereon.

All of the independent claims on appeal, namely 37, 52, 72, and 74, contain limitations that the bag must be "premanufactured orange in color," have "facial indicia," have openings suitable for filling with trash material, and that when filled, the bag must have a generally rounded appearance, like a pumpkin. Independent claims 37, 52, and 72 add the limitation that the bag's height must at least 36 inches. Claim 72 requires that the bag be made of a "weatherproof material," and claim 74, as shown above, requires that the bag be "waterproof." Claim 52 recites a "method of assembling" a bag with the general characteristics of apparatus claim 37.

#### B

The prior art cited by the Board includes:

- (1) pages 24-25 of a book entitled "A Handbook for Teachers of Elementary Art," by Holiday Art Activities ("Holiday"), describing how to teach children to make a "Crepe Paper Jack-O-Lantern" out of a strip of orange crepe paper, construction paper cut-outs in the shape of facial features, and "wadded newspapers" as filling;
- (2) page 73 of a book entitled "The Everything Book for Teachers of Young Children," by Martha Shapiro and Valerie Indenbaum ("Shapiro"), describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint;
- (3) U.S. Patent No. 3,349,991 to Leonard Kessler, entitled "Flexible Container" ("Kessler"), describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material;
- (4) U.S. Patent No. Des. 310,023, issued August 21, 1990 to Dembiczak ("Dembiczak '023"), a design patent depicting a bag with a jack-o'-lantern face;
- (5) U.S. Patent No. Des. 317,254, issued June 4, 1991 to Dembiczak ("Dembiczak '254"), a design patent depicting a bag with a jack-o'-lantern face; and,
- (6) Prior art "conventional" plastic lawn or trash bags ("the conventional trash bags").

Using this art, the Board affirmed the Examiner's final rejection of all the independent claims (37, 52, 72, 74) under

\*99835 U.S.C. § 103, holding that they would have been obvious in light of the conventional trash bags in view of the Holiday and Shapiro references. The Board determined that, in its view of the prior art, "the only difference between the invention presently defined in the independent claims on appeal and the orange plastic trash bags of the prior art and the use of such bags resides in the application of the facial indicia to the outer surface of the bag." *Dembiczak*, slip op. at 18. The Board further held that the missing facial indicia elements were provided by the Holiday and Shapiro references' description of painting jack-o'-lantern faces on paper bags. *See id.* at 18-19. Dependent claims 49 and 79, which include a "gussets" limitation, were considered obvious under similar reasoning, except that the references cited against them included Kessler. *See id.* at 7.

The Board also affirmed the Examiner's obviousness-type double patenting rejection of all the independent claims in light of the two Dembiczk design patents ('023 and '254) and Holiday. *See id.* at 12. The Board held that the design patents depict a generally rounded bag with jack-o'-lantern facial indicia, and that the Holiday reference supplies the missing limitations, such as the "thin, flexible material" of manufacture, the orange color, the initially-open upper end, and the trash filling material. The Board also stated that the various limitations of the dependent claims--e.g., color, the inclusion of leaves as stuffing, and the dimensions--would all be obvious variations of the depictions in the Dembiczk design patents. *See id.* at 8-9. In addition, using a two-way test for obviousness-type double patenting, the Board held that the claims of the Dembiczk design patents "do not exclude" the additional structural limitations of the pending utility claims, and thus the design patents were merely obvious variations of the subject matter disclosed in the utility claims. *See id.* at 11. The Board further upheld, on similar grounds and with the inclusion of the Kessler reference, the obviousness-type double patenting rejection of dependent claim 49. *See id.* at 12.

This appeal followed, vesting this court with jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994).

## II

[1] A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter

as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp.1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 86 S.Ct. 684, 15 L.Ed.2d 545, 148 USPO 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545, 148 USPO at 467; *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPO2d 1123, 1128 (Fed.Cir.1993). We therefore review the ultimate determination of obviousness without deference to the Board, while examining any factual findings for clear error. *See, e.g., In re Zurko*, 142 F.3d 1447, 1459, 46 USPO2d 1691, 1700 (Fed.Cir.) (en banc), cert. granted, 525 U.S. 961, 119 S.Ct. 401, 142 L.Ed.2d 326 (1998).

## A

[2] Our analysis begins in the text of section 103 quoted above, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," *see Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 USPO 90, 98 (Fed.Cir.1985), overruled on other grounds by \*999 *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 USPO2d 1097 (Fed.Cir.1998), when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 UPSQ 303, 313 (Fed.Cir.1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *Id.*

[3] Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed.Cir.1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed.Cir.1998) ("the Board must identify specifically ... the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed.Cir.1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed.Cir.1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed.Cir.1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 86 S.Ct. 684, 15 L.Ed.2d 545, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed.Cir.1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap.

[4][5] We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed.Cir.1996), *Para-Ordnance Mfg. v. SGS Importers*

*Intern., Inc.*, 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed.Cir.1995), although "the suggestion more often comes from the teachings of the pertinent references," *Rouffet*, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C.R. Bard*, 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." E.g., *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed.Cir.1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of \*1000 material fact."); *In re Sicherl*, 566 F.2d 1154, 1164, 196 USPQ 209, 217 (CCPA 1977) ("The examiner's conclusory statement that the specification does not teach the best mode of using the invention is unaccompanied by evidence or reasoning and is entirely inadequate to support the rejection."). In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal. Here, however, the Board did not make particular findings regarding the locus of the suggestion, teaching, or motivation to combine the prior art references.

[6] All the obviousness rejections affirmed by the Board resulted from a combination of prior art references, e.g., the conventional trash or yard bags, and the Holiday and Shapiro publications teaching the construction of decorated paper bags. See *Dembiczak*, slip op. at 6-7. To justify this combination, the Board simply stated that "the Holiday and Shapiro references would have suggested the application of ... facial indicia to the prior art plastic trash bags." *Id.* at 18-19. However, rather than pointing to specific information in Holiday or Shapiro that suggest the combination with the conventional bags, the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other--in combination with each other and the conventional

trash bags--described all of the limitations of the pending claims. *See id.* at 18-28. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the children's art references (Holiday and Shapiro) with the conventional trash or lawn bag references, nor does the Board make specific--or even inferential--findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness analysis. *See, e.g., Pro-Mold & Tool, 75 F.3d at 1573, 37 USPQ2d at 1630.*

To the contrary, the obviousness analysis in the Board's decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. For example, the Board finds that the Holiday bag reference depicts a "premanufactured orange" bag material, see *Dembiczak*, slip op. at 21, finds that Shapiro teaches the use of paper bags in various sizes, including "large", see *id.* at 22-23, and concludes that the substitution of orange plastic for the crepe paper of Holiday and the paper bags of Shapiro would be an obvious design choice, see *id.* at 24. Yet this reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with the conventional trash or lawn bags to yield the claimed invention. *See Rouffet, 149 F.3d at 1357, 47 USPQ2d at 1459* (noting Board's failure to explain, when analyzing the prior art, "what specific understanding or technical principle ... would have suggested the combination"). Because we do not discern any finding by the Board that there was a suggestion, teaching, or motivation to combine the prior art references cited against the pending claims, the Board's conclusion of obviousness, as a matter of law, cannot stand. *See C.R. Bard, 157 F.3d at 1352, 48 USPQ2d at 1232; Rouffet, 149 F.3d at 1359, 47 USPQ2d at 1459; Fritch, 972 F.2d at 1265, 23 USPQ2d at 1783; Fine, 837 F.2d at 1075, 5 USPQ2d at 1600; Ashland Oil, 776 F.2d at 297, 227 USPQ at 667.*

## B

[7] The Commissioner of Patents and Trademarks ("Commissioner") attempts to justify the Board's decision

on grounds \*1001 different from that relied upon by the Board, arguing that one of ordinary skill in the art would have been motivated to combine the references. Of course, in order to do so, the Commissioner must do what the Board did not do below: make specific findings of fact regarding the level of skill in the art ("a designer and manufacturer of trash and leaf bags, particularly one specializing in the ornamental and graphic design of such bags"), Resp't Br. at 14, the relationship between the fields of conventional trash bags and children's crafts, respectively ("[t]he artisan would also have been well aware of the ancillary, corollary, and atypical uses of 'trash' bags such as their application in hobby and art projects"), Resp't Br. at 15, and the particular features of the prior art references that would motivate one of ordinary skill in a particular art to select elements disclosed in references from a wholly different field ("a designer and manufacturer of trash and leaf bags would have recognized the paper bag in Shapiro to be a trash bag and therefore would have been motivated to combine it with the admitted prior art plastic trash and leaf bags to arrive at the claimed invention"), Resp't Br. at 15. The Commissioner also appears to cite additional references in support of his obviousness analysis, noting that at least two design patents (in the record but not cited against the presently pending claims) teach the placement of "graphical information, including text, designs, and even facial indicia, to colored bags." Resp't Br. at 16. This new analysis, apparently cut from whole cloth in view of appeal, does little more than highlight the shortcomings of the decision below, and we decline to consider it. *See, e.g., In re Robertson, 169 F.3d 743, 746, 49 USPQ2d 1949, 1951 (Fed.Cir.1999)* ("We decline to consider [the Commissioner's] newly-minted theory as an alternative ground for upholding the agency's decision."); *In re Soni, 54 F.3d 746, 751, 34 USPQ2d 1684, 1688 (Fed.Cir.1995); In re Hounsfeld, 699 F.2d 1320, 1324, 216 USPQ 1045, 1049 (Fed.Cir.1983)* (rejecting an "attempt[ ] by the Commissioner 'to apply a new rationale to support the rejection.' "); see also *35 U.S.C. § 144 (1994)* (an appeal to the Federal Circuit "is taken on the record before The Patent and Trademark Office"). Because the Board has not established a prima facie case of obviousness, *see In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed.Cir.1993)* ("The PTO bears the burden of establishing a case of prima facie obviousness."), we therefore reverse the

obviousness rejections, and have no need to address the parties' arguments with respect to secondary factors.

### III

[8][9] Dembiczak also asks this court to reverse the Board's rejection of the pending claims for obviousness-type double patenting, which is a judicially-created doctrine that seeks to prevent the applicant from expanding the grant of the patent right beyond the limits prescribed in Title 35. See, e.g., *In re Braat*, 937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed.Cir.1991); *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed.Cir.1985). See also 35 U.S.C. § 154(a)(2) (Supp.1998) (discussing patent term). The doctrine prohibits claims in a second patent which define "merely an obvious variation" of an invention claimed by the same inventor in an earlier patent. *Braat*, 937 F.2d at 592, 19 USPQ2d at 1292 (quoting *In re Vogel*, 57 C.C.P.A. 920, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970)). Thus, unless a claim sought in the later patent is patentably distinct from the claims in an earlier patent, the claim must be rejected. See *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed.Cir.1993); *Vogel*, 422 F.2d at 441, 164 USPQ at 622. This question is one of law, which we review de novo. See *Goodman*, 11 F.3d at 1052, 29 USPQ2d at 2015; *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1165, 1179, 26 USPQ2d 1018, 1029 (Fed.Cir.1993).

### \*1002 A

[10][11] The law provides that, in some very rare cases, obvious-type double patenting may be found between design and utility patents. See *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 939-40, 220 USPQ 481, 487 (Fed.Cir.1983) (noting that, while theoretically possible, "[d]ouble patenting is rare in the context of utility versus design patents"); *In re Thorington*, 57 C.C.P.A. 759, 418 F.2d 528, 536-37, 163 USPQ 644, 650 (CCPA 1969) (Double patenting between a design and utility patent is possible "if the features producing the novel aesthetic effect of a design patent or application are the same as those recited in the claims of a utility patent or application as producing a novel structure."); *In re Phelan*, 40 C.C.P.A. 1023, 205 F.2d 183, 98 USPQ 156 (CCPA 1953); *In re Barber*, 81 F.2d 231, 28 USPQ 187 (CCPA 1936); *In re Hargraves*, 53 F.2d 900, 11 USPQ 240 (CCPA 1931). In these cases, a "two-way" test is

applicable. See *Carman*, 724 F.2d at 940, 220 USPQ at 487. Under this test, the obviousness-type double patenting rejection is appropriate only if the claims of the two patents cross-read, meaning that "the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the other patent, and vice versa." *Id.*, 724 F.2d 932, 220 USPQ at 487. See also *Braat*, 937 F.2d at 593, 19 USPQ2d at 1292 (explaining two-way test).

### B

In making its double patenting rejection, the Board concluded that all but one of the pending claims of Dembiczak's utility application would have been merely an obvious variation of the claims of the earlier-issued design patents--the Dembiczak '023 and '254 references--in light of the Holiday reference. The remaining claim, dependent claim 49, was judged obvious in light of the combination of the Dembiczak design patents, Holiday, and the Kessler reference.

[12][13] Acknowledging that the two-way test was required by *Carman*, 724 F.2d at 940, 220 USPQ at 487, the Board concluded that "the design claimed in each of appellants' design patents does not exclude the features pertaining to the construction and color of the bag, the use of a plastic material for making the bag, the size or thickness of the bag ... or the use of various types of filling material.... The particular details of the facial indicia would have been a matter of design choice as evidenced by the Holiday handbook," and that therefore, in view of Holiday, the claims of the design patents were obvious variants of the pending utility patent claims. See *Dembiczak*, slip op. at 11. We disagree. In order for a design to be unpatentable because of obviousness, there must first be a basic design reference in the prior art, the design characteristics of which are "basically the same as the claimed design." *In re Borden*, 90 F.3d 1570, 1574, 39 USPQ2d 1524, 1526 (Fed.Cir.1996); *In re Rosen*, 673 F.2d 388, 391, 213 USPQ 347, 350 (CCPA 1982). The phrase "having facial indicia thereon" found in the claims of the pending utility application is not a design reference that is "basically the same as the claimed design." *Borden*, 90 F.3d at 1574, 39 USPQ2d at 1526. In fact, it describes precious little with

respect to design characteristics. The Board's suggestion that the design details were simply "a matter of design choice" evinces a misapprehension of the subject matter of design patents. *E.g., Carman*, 724 F.2d at 939 n. 13, 220 USPQ at 486 n. 13 ("Utility patents afford protection for the mechanical structure and function of an invention whereas design patent protection concerns the ornamental or aesthetic features of a design.") Indeed, we note that the two design patents at issue here--the Dembiczak '023 and '254 patents--were considered nonobvious over each other, and were even the subject of a restriction requirement. *See 35 U.S.C. § 121 (1994)* ("If two or more independent and distinct inventions are claimed in one \*1003 application, the Commissioner may require the application to be restricted to one of the inventions."); 37 C.F.R. § 1.142. The position adopted by the Board--that a textual description of facial indicia found in the claims of the utility patent application makes obvious the specific designs claimed in the (patentably distinct) Dembiczak design patents--would presumably render obvious, or even anticipate, all design patents where a face was depicted on a bag. But this, of course, is not the law; the textual description cannot be said to be a reference "basically the same as the claimed design," of the design patents at issue here. *Borden*, 90 F.3d at 1574, 39 USPQ2d at 1526 (internal quotation marks omitted). The Board's conclusion of obviousness is incorrect.

Because we find that the Board erred in concluding that the design patents were obvious variants of the pending utility claims, we need not address the other prong of the two-way double patenting test--whether the pending utility claims are obvious variations of the subject matter claimed in the design patents. *See Carman*, 724 F.2d at 939, 220 USPQ at 487 (both prongs of the two-way test required for obviousness-type double patenting). The double patenting rejections are reversed.

#### IV

Because there is no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims, the obviousness rejections are reversed. In addition, because the Board misapprehended the test for obviousness-type double patenting, and because the pending utility claims do not

render obvious the design patents, the double patenting rejections are also reversed.

#### REVERSED.

175 F.3d 994, 50 U.S.P.Q.2d 1614

#### **Briefs and Other Related Documents ([Back to top](#))**

- [1998 WL 34099977](#) (Appellate Brief) Reply Brief for Appellants Anita Dembiczak and Benson Zinbarg (Dec. 04, 1998)[Original Image of this Document \(PDF\)](#)
- [1998 WL 34099980](#) (Appellate Brief) Brief for Appellee Commissioner of Patents and Trademarks (Nov. 16, 1998)[Original Image of this Document \(PDF\)](#)
- [1998 WL 34099981](#) (Appellate Brief) Brief for Appellants Anita Dembiczak and Benson Zinbarg (Sep. 14, 1998)[Original Image of this Document with Appendix \(PDF\)](#)
- [98-1498](#) (Docket) (Jul. 14, 1998)

END OF DOCUMENT



Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL For FY 2006

Applicant claims small entity status. See 37 CFR 1.27

<b>TOTAL AMOUNT OF PAYMENT</b>	(\$ 500)
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<i>Complete if Known</i>	
Application Number	10/006,992
Filing Date	December 6, 2001
First Named Inventor	STARK, LAWRENCE W.
Examiner Name	Shay, David M.
Art Unit	3739
Attorney Docket No.	018158-018610US

**METHOD OF PAYMENT** (check all that apply)

Check    Credit Card    Money Order    None    Other (please identify): \_\_\_\_\_  
 Deposit Account   Deposit Account Number: 20-1430   Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below    Charge fee(s) indicated below, except for the filing fee  
 Charge any additional fee(s) or underpayments of fee(s)    Credit any overpayments  
 under 37 CFR 1.16 and 1.17

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**FEE CALCULATION** (All the fees below are due upon filing or may be subject to a surcharge.)**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

<u>Application Type</u>	<u>FILING FEES</u>		<u>SEARCH FEES</u>		<u>EXAMINATION FEES</u>		
	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Fees Paid (\$)</u>
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

**2. EXCESS CLAIM FEES****Fee Description**

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Fee (\$)</u>
	-20 or HP =	x	=	50	25	
HP = highest number of total claims paid for, if greater than 20				200	100	
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	360	180	

$$\text{Fee Paid ($)} = \frac{\text{Fee ($)}}{50} \times 20 = \text{Fee Paid ($)}$$

-20 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of total claims paid for, if greater than 20

$$\text{Fee Paid ($)} = \frac{\text{Fee ($)}}{50} \times 3 = \text{Fee Paid ($)}$$

Indep. Claims      Extra Claims      Fee (\$)      Fee Paid (\$)

-3 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

$$\text{Fee Paid ($)} = \frac{\text{Fee ($)}}{50} \times 50 = \text{Fee Paid ($)}$$

Total Sheets      Extra Sheets      Number of each additional 50 or fraction thereof      Fee (\$)      Fee Paid (\$)

- 100 = \_\_\_\_\_ / 50 = \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

**4. OTHER FEE(S)**

Non-English Specification,    \$130 fee (no small entity discount)      \_\_\_\_\_

Other (e.g., late filing surcharge): Filing a brief in support of an appeal      500

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent) 42,396	Telephone 303-571-4000
Name (Print/Type)	Nathan S. Cassell		Date March 21, 2006